

MEDICATION GUIDE
INVOKANA™ (in-vo-KAHN-uh)
(canagliflozin)
Tablets

What is the most important information I should know about INVOKANA?

INVOKANA can cause important side effects, including:

- **Dehydration.** INVOKANA can cause some people to have dehydration (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, lightheaded, or weak, especially when you stand up (orthostatic hypotension).

You may be at higher risk of dehydration if you:

- have low blood pressure
 - take medicines to lower your blood pressure, including diuretics (water pill)
 - are on low sodium (salt) diet
 - have kidney problems
 - are 65 years of age or older
- **Vaginal yeast infection.** Women who take INVOKANA may get vaginal yeast infections. Symptoms of a vaginal yeast infection include:
 - vaginal odor
 - white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)
 - vaginal itching
 - **Yeast infection of the penis (balanitis or balanoposthitis).** Men who take INVOKANA may get a yeast infection of the skin around the penis. Certain men who are not circumcised may have swelling of the penis that makes it difficult to pull back the skin around the tip of the penis. Other symptoms of yeast infection of the penis include:
 - redness, itching, or swelling of the penis
 - rash of the penis

- foul smelling discharge from the penis
- pain in the skin around penis

Talk to your doctor about what to do if you get symptoms of a yeast infection of the vagina or penis. Your doctor may suggest you use an over-the-counter antifungal medicine. Talk to your doctor right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

What is INVOKANA?

- INVOKANA is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- INVOKANA is not for people with type 1 diabetes.
- INVOKANA is not for people with diabetic ketoacidosis (increased ketones in blood or urine).
- It is not known if INVOKANA is safe and effective in children under 18 years of age.

Who should not take INVOKANA?

Do not take INVOKANA if you:

- are allergic to canagliflozin or any of the ingredients in INVOKANA. See the end of this Medication Guide for a list of ingredients in INVOKANA. Symptoms of allergic reaction to INVOKANA may include:
 - rash
 - raised red patches on your skin (hives)
 - swelling of the face, lips, tongue, and throat that may cause difficulty in breathing or swallowing
- have severe kidney problems or are on dialysis.

What should I tell my doctor before taking INVOKANA?

Before you take INVOKANA, tell your doctor if you:

- have kidney problems
- have liver problems

- are on a low sodium (salt) diet. Your doctor may change your diet or your dose of INVOKANA.
- have ever had an allergic reaction to INVOKANA
- have other medical conditions
- are pregnant or plan to become pregnant. It is not known if INVOKANA will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if INVOKANA passes into your breast milk. Talk with your doctor about the best way to feed your baby if you are taking INVOKANA.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

INVOKANA may affect the way other medicines work, and other medicines may affect how INVOKANA works. Especially tell your doctor if you take:

- diuretics (water pills)
- rifampin (used to treat or prevent tuberculosis)
- phenytoin or phenobarbital (used to control seizures)
- ritonavir (Norvir[®], Kaletra[®], Lopinavir[®])* (used to treat HIV infection)
- digoxin (Lanoxin[®])* (used to treat heart problems)

Ask your doctor or pharmacist for a list of these medicines if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist when you get a new medicine.

How should I take INVOKANA?

- Take INVOKANA by mouth 1 time each day exactly as your doctor tells you to take it.
- Your doctor will tell you how much INVOKANA to take and when to take it. Your doctor may change your dose if needed.
- It is best to take INVOKANA before the first meal of the day.

- Your doctor may tell you to take INVOKANA along with other diabetes medicines. Low blood sugar can happen more often when INVOKANA is taken with certain other diabetes medicines. See **“What are the possible side effects of INVOKANA?”**
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take two doses of INVOKANA at the same time. Talk to your doctor if you have questions about a missed dose.
- If you take too much INVOKANA, call your doctor or go to the nearest hospital emergency room right away.
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor’s instructions.
- Stay on your prescribed diet and exercise program while taking INVOKANA.
- Check your blood sugar as your doctor tells you to.
- INVOKANA will cause your urine to test positive for glucose.
- Your doctor may do certain blood tests before you start INVOKANA and during treatment as needed. Your doctor may change your dose of INVOKANA based on the results of your blood tests.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.

What are the possible side effects of INVOKANA?

INVOKANA may cause serious side effects including:

See **“What is the most important information I should know about INVOKANA?”**

- **kidney problems**
- **a high amount of potassium in your blood (hyperkalemia)**

- **low blood sugar (hypoglycemia).** If you take INVOKANA with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take INVOKANA.

Signs and symptoms of low blood sugar may include:

- headache
 - drowsiness
 - weakness
 - dizziness
 - confusion
 - irritability
 - hunger
 - fast heart-beat
 - sweating
 - shaking or feeling jittery
- **serious allergic reaction.** If you have any symptoms of a serious allergic reaction, stop taking INVOKANA and call your doctor right away or go to the nearest hospital emergency room. See **“Who should not take INVOKANA?”**. Your doctor may give you a medicine for your allergic reaction and prescribe a different medicine for your diabetes.

The most common side effects of INVOKANA include:

- vaginal yeast infections and yeast infections of the penis (See **“What is the most important information I should know about INVOKANA?”**)
- urinary tract infection
- changes in urination, including urgent need to urinate more often, in larger amounts, or at night

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of INVOKANA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Janssen Pharmaceuticals, Inc. at 1-800-526-7736.

How should I store INVOKANA?

- Store INVOKANA at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep INVOKANA and all medicines out of the reach of children.**

General information about the safe and effective use of INVOKANA.

Medicines are sometimes prescribed for purposes other than those listed in the Medication Guide. Do not use INVOKANA for a condition for which it was not prescribed. Do not give INVOKANA to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about INVOKANA. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about INVOKANA that is written for healthcare professionals.

For more information about INVOKANA, call 1-800-526-7736 or visit our website at www.invokana.com.

What are the ingredients of INVOKANA?

Active ingredient: canagliflozin

Inactive ingredients: croscarmellose sodium, hydroxypropyl cellulose, lactose anhydrous, magnesium stearate, and microcrystalline cellulose. In addition, the tablet coating contains iron oxide yellow E172 (100 mg tablet only), macrogol/PEG, polyvinyl alcohol, talc, and titanium dioxide.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Active ingredient made in Belgium.

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778

Licensed from Mitsubishi Tanabe Pharma Corporation

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